REMARKS

Claims 1, 3, and 7, as amended, and claims 17, 19, and 22 are pending in the instant application. No new matter has been added as a result of the above-described amendments. The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

1. Rejections of claims 1, 3, 7, 17, 19, and 22 under 35 U.S.C. § 112, first paragraph

The Office Action asserts a rejection of claims 1, 3, 7, 17, 19, and 22 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Action states that while claim 1 requires that the reagent comprise only two of the six groups of recited "plurality of genomic HPV DNA probes sets," the specification exemplifies a reagent comprising all six of the recited probe sets and does not contemplate or disclose reagents comprising any two, three, four, or five of the recited probe sets. The Action, therefore, asserts that claim 1 fails to comply with the written description requirement. The Action also asserts that because the specification does not contemplate a reagent comprising only two of the six probe sets that also hybridizes to HPV types 39, 45, 52, 56, 58, 59, 68, and 70, claim 3 contains new matter. The Action further asserts that because the extent of cross-hybridization along the length of HPV types 39, 45, 52, 56, 58, 59, 68 and 70 is not discussed in the specification, the limitation in claim 3 that the probes also hybridize to substantially all of the full-length genomic sequence of HPV types 39, 45, 52, 56, 58, 59, 68 and 70 constitutes new matter.

Applicants note that claim 1, as originally filed, recited "[a] reagent for detecting human papilloma virus DNA in a cell sample which indicates the patient providing the cell sample is at risk for cancer comprising; a plurality of DNA probes capable of specifically hybridizing to high-risk HPV DNA but not low-risk HPV DNA." Applicants also note that the instant specification teaches that the claimed invention relates to reagents comprising a plurality of genomic HPV DNA probe sets in which the cross-reactivity of the genomic HPV DNA probe sets is exploited to permit detection of HPV types that are associated with malignancy but which lack genomic sequences that are completely complementary to the genomic HPV DNA probe sets (page 4). Applicants further

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note that the instant specification teaches the ability of individual genomic HPV DNA probe sets derived from HPV types 16, 18, 31, 33, 35, or 51 to cross-react with the genomic sequences of HPV types 16, 18, 31, 33, 35, 39, 41-45, 51, 52, 56, 58, 59, 68, and 70 (page 9, Table 1). Applicants contend, therefore, that the instant specification clearly contemplates reagents comprising various combinations of genomic HPV DNA probe sets, including a reagent comprising genomic HPV DNA probe sets derived from HPV types 16, 18, 31, 33, 35, and 51. In addition, Applicants contend that one of ordinary skill in the art could readily use the teachings in the instant specification to design other reagents that would satisfy the limitations of claim 1. Applicants, therefore, respectfully disagree with the Action's assertion that claim 1 fails to comply with the written description requirement.

Nevertheless, in an effort to expedite prosecution of the pending claims to allowance, Applicants have amended claim 1 to recite a reagent for detecting human papilloma virus (HPV) DNA in a cell sample which indicates the patient providing the cell sample is at risk for cancer, comprising a plurality of genomic HPV DNA probes sets; wherein a first genomic HPV DNA probe set comprises a plurality of nucleic acid fragments of essentially the full-length genomic sequence of HPV type 16, a second genomic HPV DNA probe set comprises a plurality of nucleic acid fragments of essentially the full-length genomic sequence of HPV type 18, a third genomic HPV DNA probe set comprises a plurality of nucleic acid fragments of essentially the full-length genomic sequence of HPV type 31, a fourth genomic HPV DNA probe set comprises a plurality of nucleic acid fragments of essentially the full-length genomic sequence of HPV type 33, a fifth genomic HPV DNA probe set comprises a plurality of nucleic acid fragments of essentially the full-length genomic sequence of HPV type 35, and a sixth genomic HPV DNA probe set comprises a plurality of nucleic acid fragments of essentially the full-length genomic sequence of HPV type 51; and wherein the nucleic acid fragments of the genomic HPV DNA probe sets do not detectably hybridize to the genomic sequence of a low-risk HPV type. Applicants contend that because amended claim 1 requires that the reagent comprise genomic HPV DNA probes sets derived from each of HPV types 16, 18, 31, 33, 35, and 51, amended claim 1 complies with the written description requirement.

Applicants have amended claim 3 to recite that "the nucleic acid molecules of the genomic HPV DNA probe sets also hybridize to the genomic sequence of HPV types 39, 45, 52, 56, 58, 59,

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68 and 70." Applicants contend that because claim 1, from which claim 3 depends, requires that the reagent comprise genomic HPV DNA probes sets derived from each of HPV types 16, 18, 31, 33, 35, and 51, and because claim 3 no longer contains the limitation that the probes hybridize to substantially all of the full-length genomic sequence of HPV types 39, 45, 52, 56, 58, 59, 68 and 70, claim 3, as amended, no longer contains new matter.

2. Rejections of claims 3, 7, 19, and 22 under 35 U.S.C. § 112, second paragraph

The Office Action asserts a rejection of claims 3, 7, 19, and 22 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The Action first asserts that the phrase "the genomic DNA HPV probes" in claims 3 and 7 lacks proper antecedent basis since claim 1 previously refers to "genomic HPV DNA probe sets," but not to genomic HPV DNA probes. The Action states that it is therefore unclear whether this phrase refers back to the probe sets recited in claim 1 or the plurality of nucleic acid molecules comprising the probe sets.

Applicants have amended claim 3 to replace the phrase "genomic HPV DNA probes" with the phrase "nucleic acid fragments of the genomic HPV DNA probe sets," and claim 7 to replace the phrase "genomic HPV DNA probes" with the phrase "nucleic acid fragments comprising each genomic HPV DNA probe set." Applicants contend that claims 3 and 7, as amended, no longer lack a proper antecedent basis, and therefore, respectfully request that this ground of rejection be withdrawn.

The Action also asserts that claim 7 is indefinite because while the claim recites proportions, proportions are considered in reference to a whole and the claim does not set forth the whole.

Applicants have amended claim 7 to recite that "the nucleic acid fragments comprising each genomic HPV DNA probe set are present in the reagent in the following proportions as a percent of total HPV DNA in the reagent." Applicants contend that claim 7, as amended, is no longer indefinite, and therefore, respectfully request that this ground of rejection be withdrawn.

Applicants respectfully contend that rejections based on 35 U.S.C. § 112, second paragraph, have been overcome by amendment and request that the Examiner withdraw all rejections made on

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this basis.

3. Rejection of claims 1, 3, 17, and 19 under 35 U.S.C. § 102

a. Rejection of claims 1, 3, 17, and 19 as being anticipated by Troncone *et al.*, as evidenced by Herrington *et al.*

The Office Action asserts a rejection of claims 1, 3, 17, and 19 under 35 U.S.C. § 102(b), as being anticipated by Troncone *et al.*, 1992, *J. Clin. Pathol.* 45:308-313, as evidence by Herrington *et al.*, 1989, *J. Clin. Pathol.* 42:592-600. The Action states that Troncone *et al.* disclose a reagent for detecting human papilloma virus DNA in a cell sample comprising a plurality of genomic DNA probe sets, wherein each probe set comprises a plurality of nucleic acid molecules that detectably hybridize to substantially all of the full-length genomic sequence of HPV types 16, 18, and 33. The Action also states that the probes disclosed by Troncone *et al.* are considered to hybridize to "substantially all" of the full-length genomic sequence as evidenced by the Herrington *et al.* reference, which discloses labeling of whole genomic HPV probes using nick translation, and which is cited by Troncone *et al.* in reference to the labeling of the probes in their reagent. The Action further states that the probes disclosed by Troncone *et al.* inherently cross-hybridize to the genomic sequences of HPV types 39, 45, 52, 56, 58, 59, 68, and 70, as evidenced by the instant specification which teaches that a genomic probe set derived from HPV type 18 hybridizes to HPV types 18, 39, 45, 56, 59, 68, and 70 and a genomic probe set derived from HPV type 33 hybridizes to HPV types 16, 31, 33, 35, 45, 52, and 58, and therefore, the reagent of claim 3 is also anticipated by Troncone *et al.*

Applicants note that claim 1, as presented in Applicants' Amendment filed August 4, 2004, recited "[a] reagent . . . comprising a plurality of genomic HPV DNA probe sets, wherein each probe set comprises a plurality of nucleic acid molecules that *detectably* hybridize to substantially all of the full-length genomic sequence of HPV types 16, 18, 31, 33, 35, [and] 51" (emphasis added) (Applicants acknowledge that claim 1 contained a typographical error in that it recited "HPV types 16, 18, 31, 33, 35, *or* 51" instead of "HPV types 16, 18, 31, 33, 35, *and* 51"). Applicants also note that the instant specification teaches that a genomic HPV DNA probe set derived from HPV type 16 barely detects HPV types 35 and 51, a genomic HPV DNA probe set derived from HPV type 18 does

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not detect HPV types 31, 35, or 51, and a genomic HPV DNA probe set derived from HPV type 33 does not detect HPV type 51 and barely detects HPV type 35 (page 9, Table 1). Applicants contend, therefore, that because the reagent disclosed by Troncone *et al.* does not *detectably* hybridize to substantially all of the full-length genomic sequence of HPV types 16, 18, 31, 33, 35, and 51, Troncone *et al.* cannot anticipate claim 1.

Nevertheless, as described in section 1 above, Applicants have amended claim 1 to recite a reagent comprising six genomic HPV DNA probe sets derived from HPV types 16, 18, 31, 33, 35, and 51. Applicants contend that because Troncone *et al.* does not disclose a reagent comprising six genomic HPV DNA probe sets derived from HPV types 16, 18, 31, 33, 35, and 51, Troncone *et al.* does not anticipate claims 1, 3, 17, and 19. Withdrawal of this rejection is therefore respectfully solicited.

b. Rejection of claims 1, 3, 17, and 19 as being anticipated by Nuovo *et al.*

The Office Action asserts a rejection of claims 1, 3, 17, and 19 under 35 U.S.C. § 102(b), as being anticipated by Nuovo *et al.*, 1995, *J. Histotechnology* 18:105-110. The Action states that Nuovo *et al.* disclose a reagent for detecting human papilloma virus DNA in a cell sample comprising a plurality of genomic DNA probe sets, wherein each probe set comprises a plurality of nucleic acid molecules that detectably hybridize to substantially all of the full-length genomic sequence of HPV types 16, 18, 31, 33, and 35. The Action also states that Nuovo *et al.* disclose a reagent provided by Digene that is derived from the entire genome of the HPV types listed above. The Action further states that the probes disclosed by Nuovo *et al.* inherently cross-hybridize to the genomic sequences of HPV types 39, 45, 52, 56, 58, 59, 68, and 70, as evidenced by the instant specification which teaches that a genomic probe set derived from HPV type 18 hybridizes to HPV types 18, 39, 45, 56, 59, 68, and 70 and a genomic probe set derived from HPV type 33 hybridizes to HPV types 16, 31, 33, 35, 45, 52, and 58, and therefore, the reagent of claim 3 is also anticipated by Nuovo *et al.*

Applicants note that Nuovo *et al.* disclose a reagent that is derived from the entire genome of HPV types 6, 11, 16, 18, 31, 33, and 35 (as well as three other reagents that are derived from HPV types 6 and 11, HPV types 16 and 18, or HPV types 31, 33, and 35) (page 106). Applicants contend

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that because Nuovo *et al.* disclose a reagent comprising, at least in part, genomic HPV DNA probe sets derived from HPV types 6 and 11, Nuovo *et al.* does not disclose a reagent in which the nucleic acid fragments of the genomic HPV DNA probe sets do not detectably hybridize to the genomic sequence of a low-risk HPV type, and therefore, that Nuovo *et al.* does not anticipate claims 1, 3, 17, and 19. Moreover, Applicants contend that because Nuovo *et al.* also does not disclose a reagent comprising genomic HPV DNA probe sets derived from each of HPV types 16, 18, 31, 33, 35, and 51, Nuovo *et al.* does not anticipate claims 1, 3, 17, and 19. Withdrawal of this rejection is therefore respectfully solicited.

Applicants respectfully contend that rejections based on 35 U.S.C. § 102 have been overcome by amendment and request that the Examiner withdraw all rejections made on this basis.

CONCLUSIONS

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner Switzer believes it to be helpful, she is invited to contact the undersigned representative by telephone at 312-913-0001.

Respectfully submitted,
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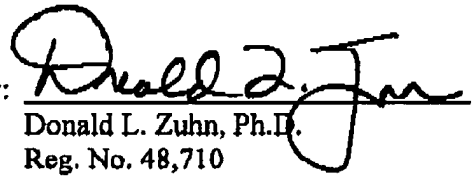
Dated: January 18, 2005

By: 
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